

Application No. 09/828,798

REMARKS

Claims 1, 3, 4 and 6-8 are pending in this application, claim 7 having been withdrawn from consideration.

I. Formal Matters

By this Amendment, claim 1 is amended. Support for these amendments to claim 1 can be found in the specification as filed, for example, at page 4, lines 19-25. Thus, no new matter is added.

Entry of the amendments is proper under 37 CFR §1.116 since the amendments: (a) place the application in condition for allowance for the reasons discussed herein; (b) do not raise any new issue requiring further search and/or consideration; and (c) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

II. Pending Claims 1, 3, 4 and 6-8 Define Patentable Subject Matter**A. Rejections Under 35 U.S.C §112**

The Office Action rejects claim 1 under 35 U.S.C. §112, first paragraph. Applicant respectfully traverses this rejection.

By this Amendment, claim 1 is amended to set forth a "health food product comprising cholic acid at a daily dose of 1 to 1,000 mg and at least one member selected from the group consisting of isoflavones and isoflavone glycosides at a daily does of 1 to 500 mg." Support for daily dosage ranges of amended claim 1 can be found in the specification as filed, for example, at page 4, lines 19-25.

Thus, amended claim 1 contains no subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventor

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had possession of the claimed invention at the time of the filing of the application.

Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

B. Rejections Under 35 U.S.C. §103

The Office Action newly rejects claims 1, 3, 4, 6 and 8 under 35 U.S.C. §103(a) over U.S. Patent 4,487,766 to Mach. Further, the Office Action newly rejects claims 1 and 6 under 35 U.S.C. §103(a) over U.S. Patent 4,487,766 to Mach in view of JP 57063057 A to Ogawa. Applicant respectfully traverses these rejections. Because the rejections are related they will be addressed together.

Independent claim 1 sets forth a "health food product comprising cholic acid at a daily dose of 1 to 1,000 mg and at least one member selected from the group consisting of isoflavones and isoflavone glycosides at a daily does of 1 to 500 mg." The combination of cholic acid and at least one member selected from the group consisting of isoflavones and isoflavone glycosides, represents Applicant's unique discovery. As demonstrated by the TABLE, located at page 10 of the specification, this combination of cholic acid and at least one member chosen from the group consisting of isoflavones or isoflavone glycosides produces biologically synergistic effects. Such a health food product, and the effects it provides, is not taught or suggested by the cited references.

Mach discloses an animal feed comprising, in pertinent part, a coarse ground soybeans and cholic acid. Mach discloses soybeans but does not disclose either of the claimed isoflavones or isoflavone glycosides, generally or specifically as soybean isoflavones or soybean isoflavone glycosides.

Mach also fails to disclose the specific combination of cholic acid and at least one of isoflavones or isoflavone glycosides, and does not disclose the combination of cholic acid and at least one of isoflavones or isoflavone glycosides at the specific daily dosages claimed.

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Although Mach discloses the percentages in which the various components of the animal feed are combined, the percentage composition does not yield a defined dose. Mach also discloses that the feed is provided ad libitum. Thus, there clearly is no specified dosing of the cholic acid or the isoflavones or isoflavone glycosides. Mach thus fails to provide either a minimum or a maximum daily dose. Nowhere does Mach disclose, teach or suggest a dose of the composition, having the specified amounts of the respective components.

Further, Mach discloses an animal feed, not intended for human use, comprising, in pertinent part, growth-promoting agent, a coarse ground soybeans and cholic acid. The goal of Mach is a growth-promoting animal feed, not a health food for human consumption. Nothing in Mach suggests that components of a growth-promoting animal feed could be formulated into a health food for human beings. Also, Mach does not contain any suggestion that the specific benefits of the claimed combination, such as those summarized in the TABLE of the specification, could be obtained either in animals or in humans, based on weight gain in animals attributed to the Mach animal feed.

The Office Action further asserts that Mach anticipates the composition that further comprises a "crude drug," because Mach discloses the inclusion of green alfalfa flour and alfalfa is known to possess certain pharmacologically active phytochemicals inherently. However, as discussed above, Mach fails to disclose the claimed combination of cholic acid and isoflavones or isoflavone glycosides, at the dosages claimed. Mach thus further does not disclose, teach or suggest the further inclusion of a crude drug in such a composition, as claimed.

Based on the teachings of Mach, one of ordinary skill in the art might, at most, find some motivation to optimize the ingredients of the animal feed of Mach to produce a synergistic effect in animal growth. However, Mach does not disclose, teach or suggest

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producing a "health food product comprising cholic acid at a daily dose of 1 to 1,000 mg and at least one member selected from the group consisting of isoflavones and isoflavone glycosides at a daily does of 1 to 500 mg." Nor is there a suggestion of the benefits to humans found with the claimed combination. Thus, Mach would not have rendered the invention of claims 1, 3, 4, 6 and 8 obvious.

For at least the same reasons discussed above with respect to claims 1, 3, 4, 6 and 8, Mach does not disclose, teach or suggest the invention of claims 1 and 6. Ogawa does not remedy the shortcomings of Mach.

Ogawa discloses an animal feed comprising, in pertinent part, ginseng and vitamin A, which, among other effects, has a growth-promoting effect and increases milk volume and fat content.

As discussed above, the combination of cholic acid and at least one member selected from the group consisting of isoflavones and isoflavone glycosides, produces biologically synergistic effects. One who is familiar with the claimed combination might expect additional synergistic effects and advantageous results by admixing the claimed combination with other active ingredients such as ginseng and/or vitamins. But neither Mach nor Ogawa discloses, teaches or suggests the claimed combination of cholic acid and at least one of isoflavones or isoflavone glycosides at the specific daily dosages claimed. Thus, additional synergistic effects would not have been expected based on Mach and Ogawa.

Based on the teachings of Mach, and of Ogawa, one of ordinary skill in the art might, at most, find motivation to combine ginseng with the animal feed comprising a growth-promoting agent of Mach to produce a synergistic effect in animal growth. But nothing in either reference discloses, teaches or suggests producing a "health food product comprising cholic acid at a daily dose of 1 to 1,000 mg and at least one member selected from the group consisting of isoflavones and isoflavone glycosides at a daily does of 1 to 500 mg." Neither

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reference suggests the benefits to humans of the claimed combination. Thus, Mach, alone or in combination with Ogawa, would not have rendered the invention of claims 1 and 6 obvious.

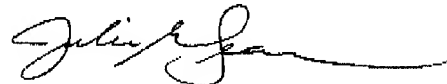
For at least these reasons, Mach, alone or in view of Ogawa, does not disclose, teach or suggest the invention of claims 1, 3, 4, 6 and 8. Accordingly, reconsideration and withdrawal of these rejections are respectfully requested.

III. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 3, 4 and 6-8 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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